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TITLE: A Randomized Effectiveness Trial of a Systems-Level Approach to Stepped Care for War-Related PTSD

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| <b>13. SUPPLEMENTARY NOTES</b>   |                         |                                 |  |   |   |
| <b>14. ABSTRACT</b><br>Over the course of the last year, the study team concluded enrollment at all study sites as well as data collection for the 3- and 6-month follow-up assessments. Data collection for the 12-month assessment occurred during this period, concluding at 5 of the 6 sites (Joint Base Lewis-McChord, Ft. Bliss, Ft. Carson, Ft. Stewart, and Ft. Bragg) and is ongoing at the remaining site (Ft. Campbell). As of August 31, 2014, 1,320 total referrals across the six sites had been received; 666 participants had been enrolled and randomized into the study (332 participants into the STEPS UP arm; 334 participants into the optimized usual care arm); 618 participants completed the 3-month follow-up assessment; 600 participants completed the 6-month follow-up; and 573 participants completed the 12-month follow-up. Plans for analyses and presentations were developed and several presentations were made. A journal paper was submitted describing the design of the trial. |                         |                                 |  |   |   |
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## **INTRODUCTION:**

The purpose of the STEPS UP (STepped Enhancement of PTSD Services Using Primary Care) trial is to compare centralized telephonic care management with preference-based stepped PTSD and depression care to optimized usual care (OUC). We hypothesize that the STEPS UP intervention will lead to improvements in (1) PTSD and depression symptom severity (primary hypothesis); (2) anxiety and somatic symptom severity, alcohol use, mental health functioning, work functioning; (3) costs and cost-effectiveness. We further hypothesize that qualitative data will show (4) patients, their family members, and participating clinicians find that the STEPS UP intervention is an acceptable, effective, and satisfying approach to deliver and receive PTSD and depression care.

STEPS UP is a six-site, two-parallel arm (N = 666) randomized controlled effectiveness trial with 3-month, 6-month, and 12-month follow-ups comparing centralized telephonic stepped-care management to optimized usual PTSD and depression care. In addition to the existing PTSD and depression treatment options, STEPS UP includes web-based cognitive behavioral self-management, telephone cognitive-behavioral therapy, continuous RN nurse care management, and computer-automated care management support. Both arms can refer patients for mental health specialty care as needed, preferred, and available. The study uses sites currently running RESPECT-Mil, the existing military primary care-mental health services practice network, to access site health care leaders and potential study participants at the 6 study sites.

If effective, we expect that STEPS UP will increase the percentage of military personnel with unmet PTSD- and depression-related health care needs who get timely, effective, and efficient PTSD and depression care. Our real-world primary care effectiveness emphasis will prevent the Institute of Medicine's so called "15 year science to service gap." If successful, STEPS UP could roll out immediately, reinforcing and facilitating pathways to PTSD and depression recovery.

## **KEYWORDS:**

Collaborative care, PTSD, military, depression, primary care, care management, stepped care, telehealth, OIF, OEF, preference-based treatment, cost effectiveness, web-based treatment, telephonic CBT, evidence-based treatment.

## **OVERALL PROJECT SUMMARY:**

The STEPS UP study is currently in the follow-up data collection phase. The study team completed recruitment and enrollment of 666 participants (332 participants in the STEPS UP intervention arm; 334 participants in the Optimized Usual Care [OUC] arm) in August 2013. As of January 2014, 665 participants had exited the 3-month follow-up window (one participant was withdrawn due to incarceration); 618 participants completed the 3-month follow-up assessment (229 at JBLM, 106 at Ft. Bliss, 197 at Ft. Campbell, 17 at Ft. Carson, 46 at Ft. Stewart, and 23 at Ft. Bragg), for an overall 3-month follow-up completion rate of 93%. As of March 2014, all 665 participants had also exited the 6-month follow-up window; 600 participants completed the 6-month follow-up assessment (221 at JBLM, 104 at Ft. Bliss, 192 at Ft. Campbell, 15 at Ft. Carson, 45 at Ft. Stewart, and 23 at Ft. Bragg), for an overall 6-month follow-up completion rate

of 90%. A total of 664 participants (one additional participant was withdrawn due to incarceration) became eligible for the 12-month follow-up; 573 participants have completed the 12-month follow-up assessment (208 at JBLM, 102 at Ft. Bliss, 184 at Ft. Campbell, 15 at Ft. Carson, 42 at Ft. Stewart, and 22 at Ft. Bragg), for an overall 12-month follow-up completion rate of 86%. As of August 31, 2014, 2 participants, both at Ft. Campbell, are pending completion of the 12-month follow-up assessment (1 in the STEPS UP intervention arm and 1 in the OUC arm). We anticipate completing follow-up data collection early in the next quarter and then will conduct data analyses of the trial using all completed assessments.

Study investigators continued to participate in multiple routine weekly conference calls and other communications as necessary to ensure timely completion of all tasks throughout the year. During the past year, RTI continued ongoing routine maintenance and evaluation of the study website, conducted follow up assessments with study participants, and continued to refine strategies for obtaining follow-up assessments at each study location. RTI also engaged in data editing and preparation of data files and codebooks for the baseline, 3-month, 6-month, and 12-month follow-up assessments.

## **DSMB**

During the past year, the STEPS UP team held one meeting with the DSMB on January 28, 2014. During that meeting, main topics of discussion included progress to date on the study, DSMB report draft, and Design Manuscript draft. In February 2014, the DSMB finalized a report which summarized the first two DSMB meetings. We plan to hold the next DSMB meeting in the next quarter, once follow-up data collection is complete.

## **Request to Exercise No Cost Time Extension and Updated Joint SOW**

On February 28, 2014, RTI's Contracts Department sent Mr. Lance Nowell a letter requesting RTI's decision to exercise a No Cost Time Extension (NCE) under the terms of the grant and a revised SOW that was coordinated with our partnering organizations (Defense Health Clinical Center (DHCC)-Henry Jackson Foundation and RAND Corporation). The reason for the updated joint SOW was that Mr. Nowell identified that among the three partnering institutions on this grant, there were inconsistent dates on the SOW and he requested consistency, which all three institutions provided.

## **Change of Scientific Monitor**

On April 16, 2014, Dr. Jordan Irvin informed the Partnering PIs that he was leaving the CDMRP. His last day, he stated was 15 April 2014. He informed them that the new Science Officer point of contact would be Jonathan Ryder.

## **Manuscripts and Presentations**

The study team held a series of meetings and discussions about ideas for papers and presentations. These resulted in a series of brief abstracts describing planned papers and the planned analysis approach for these papers once all of the follow up data collection is completed.

The study team prepared and submitted a manuscript describing the overall design and methods of the STEPS UP study to *Contemporary Clinical Trials* in July 2014; investigators are preparing revisions to this manuscript. In preparation for the end of data collection, the team has begun drafting a manuscript describing the primary outcomes of the study; investigators plan to submit this manuscript to a high-impact journal once data collection and analysis are complete.

A presentation titled “DoD STEPS-UP: Design, Roll-Out and Early Lessons from a Randomized Effectiveness Trial of Collaborative PTSD Care in Army Primary Care,” was presented as a part of the symposium “Interventions for PTSD in Primary Care Medical Settings: Implementation and Early Effectiveness Outcomes” at the 29<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS), which was held in November 2013 in Philadelphia, PA. A second presentation at the Military Health System Research Symposium (MHSRS) in August 2014 in Ft. Lauderdale, FL. described the STEPS UP study design. Additionally, a symposium titled “Implementing Traumatic Stress Services in Military Primary Care: Treatment & Trials” was accepted for presentation at the 30<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS) which will be held in November 2014 in Miami, FL. As part of this symposium, investigators will present on study-related topics including study design and early findings, results from the qualitative portion of the study, and suicide risk and correlates based on study eligibility data.

## **IRB**

In February 2014, the WRNMMC IRB approved an amendment which provided the DHCC Data Safeguarding Plan for data sharing. This plan describes how investigators at DHCC will obtain datasets from RTI and handle those datasets when conducting analyses. RAND, University of Washington, and BVARI have also received IRB approval from their institutions of their Data Safeguarding Plans. During the second quarter, RAND finalized a Data Transfer Agreement with RTI for the study datasets. During the third quarter, BVARI finalized their Data Transfer Agreement with RTI. During the fourth quarter, DHCC and University of Washington finalized their Data Transfer Agreement with RTI. All institutions now have access to the eligibility, baseline, 3-month, and 6-month datasets. We expect all institutions to have access to the 12-month dataset within the next quarter, once follow-up data collection is complete.

During the last year, RTI’s IRB, all local site IRBs, and HRPO approved the study in continuing review; the WRNMMC protocol and each site package have a new expiration date of 7 May 2015.

## **Plans for Next Quarter**

During the next quarter, we plan to complete the 12-month follow-ups at the remaining study site (Ft. Campbell) and conduct data analyses on the full dataset. We will also continue to ensure compliance with all IRB administrative requirements. The study team will also continue work on multiple publications and presentations, and will prepare and disseminate materials to

provide site, military, and MHS leaders with information about the trial results and the STEPS UP intervention program.

### **KEY RESEARCH ACCOMPLISHMENTS:**

There are not yet any clear scientific findings resulting from this research as we are still in the data collection phase.

### **CONCLUSION:**

There are no conclusions to report at this time, as the study is still in the data collection phase. Investigators expect to complete data collection and conduct analyses in the next quarter.

### **PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:**

RTI team members contributed to the following which was presented at the 29<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS) in November 2013 in Philadelphia, PA:

Engel CC, Freed MC, Lane B, Jaycox L, Bray R, Zatzick D, Litz B. (November 2013). DoD STEPS-UP: Design, Roll-Out and Early Lessons from a Randomized Effectiveness Trial of Collaborative PTSD Care in Army Primary Care. Part of ISTSS Symposium: Interventions for PTSD in Primary Care Medical Settings: Implementation and Early Effectiveness Outcomes. Meredith L (chair) & Zatzick D (discussant). 29<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS), Philadelphia, PA.

The STEPS UP team submitted the following manuscript to *Contemporary Clinical Trials* in July 2014 which received favorable reviews and is pending revisions:

Engel CC, Bray RM, Jaycox L, Freed MC, Zatzick D, Lane ME, Brambilla D, Rae Olmsted K, Vandermaas-Peeler R, Litz B, Tanielian T, Belsher BE, Evatt DP, Novak LA, Unützer J, Katon WJ. Collaborative primary care for depression and posttraumatic stress disorder in the U.S. military health system: Design and baseline findings of a multisite randomized effectiveness trial.

RTI team members contributed to the following which was presented at the Military Health System Research Symposium (MHSRS) in August 2014 in Ft. Lauderdale, FL:

Freed M, Engel C, Bray RM, Jaycox L, Zatzick D, Lane M, Brambilla D, Rae Olmsted K, Vandermaas-Peeler R, Litz B, Tanielian T, Belsher B, Evatt D, Novak L, Unutzer J, Katon W. (August 2014). Collaborative Primary Care for Depression and PTSD in the U.S. Military Health System: Design and Early Findings from STEPS UP, a Multisite Randomized Effectiveness Trial. Presented at Military Health System Research Symposium (MHSRS), Ft. Lauderdale, FL.

RTI team members contributed to the following presentation that was accepted as part of a symposium titled “Implementing Traumatic Stress Services in Military Primary Care: Treatment & Trials” at the 30<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS) in November 2014 in Miami, FL:

Freed MC, Engel CC, Belsher B, Evatt D, Wortmann J, Novak L, Jaycox LH, Bray RM. (November 2014). Suicide Risk and Correlates to PTSD, Depression, and Alcohol Misuse in Military Primary Care Populations. Part of ISTSS Symposium: Implementing Traumatic Stress Services in Military Primary Care: Treatment & Trials. Engel CC (chair). 30<sup>th</sup> Annual Meeting of the International Society for Traumatic Stress Studies (ISTSS), Miami, FL.

#### **INVENTIONS, PATENTS AND LICENSES:**

Nothing to report.

#### **REPORTABLE OUTCOMES:**

Nothing to report.

#### **OTHER ACHIEVEMENTS:**

Nothing to report.

#### **REFERENCES:**

Curry, J. C., Engel, C. C., & Zatzick, D. (in press). Stigma and barriers to care - collaborative care. In S. Cozza, M. Goldenberg, & R. Ursano (Eds.), *Clinical manual for the care of military service members, veterans, and their families*. Arlington, VA: American Psychiatric Publishing.

Zatzick, D., Rivara, F., Jurkovich, G., Russo, J., Geiss, S., Wang, J., et al. (2011). Enhancing the population impact of collaborative care interventions: mixed method development and implementation of stepped care targeting posttraumatic stress disorder and related comorbidities after acute trauma. *General Hospital Psychiatry*, 33, 123-134.

Engel C. C, T. Oxman, et al. (2008). Feasibility of collaborative care for depression and post-traumatic stress disorder in military primary care: The RESPECT-Mil Project. *Military Medicine*, 173(10), 935-940.

Tanielian, T. & Jaycox, L., Eds. (2008). "Invisible Wounds of War: Psychological and Cognitive Injuries, Their Consequences, and Services to Assist Recovery." RAND/MG-720-CCF (available at <http://veterans.rand.org>)

Litz, B. T., Engel, C. C., Bryant, R., & Papa, A. (2007). A Randomized, Controlled Proof-of-Concept Trial of an Internet-Based, Therapist-Assisted Self-Management Treatment for Posttraumatic Stress Disorder. *American Journal of Psychiatry*, 164(11), 1676-1683.

#### **APPENDICES:** n/a